



Webinar on personal protective equipment production

WHO PPE specifications

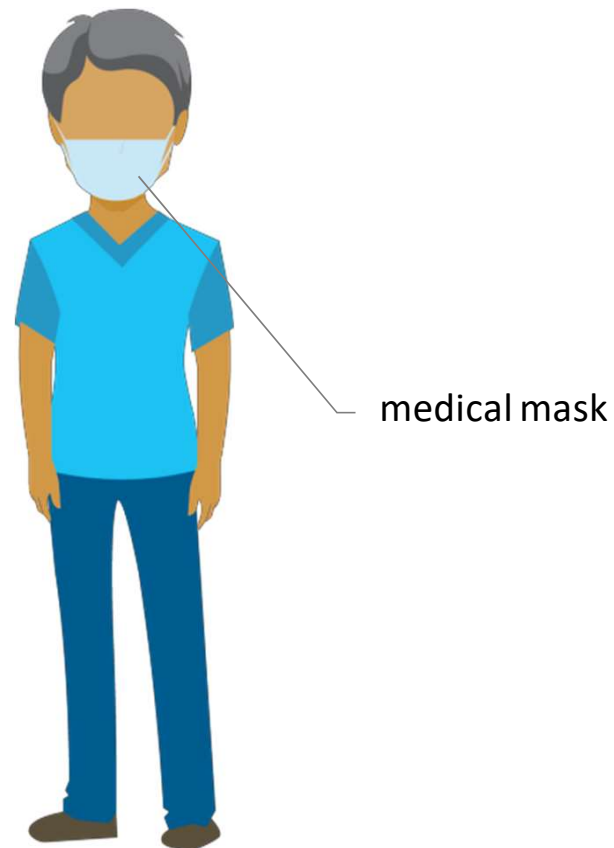
4 May 2020

Objectives

- ❑ **Discuss which PPE items are recommended for protection against COVID-19**
- ❑ **Share WHO disease commodity package for COVID-19**
- ❑ **Present the WHO specifications for main PPE items planned for local production**
- ❑ **Give an example of how the specifications translate into parameters for production and testing**
- ❑ **Update on Bangladesh efforts to develop minimum testing parameters**

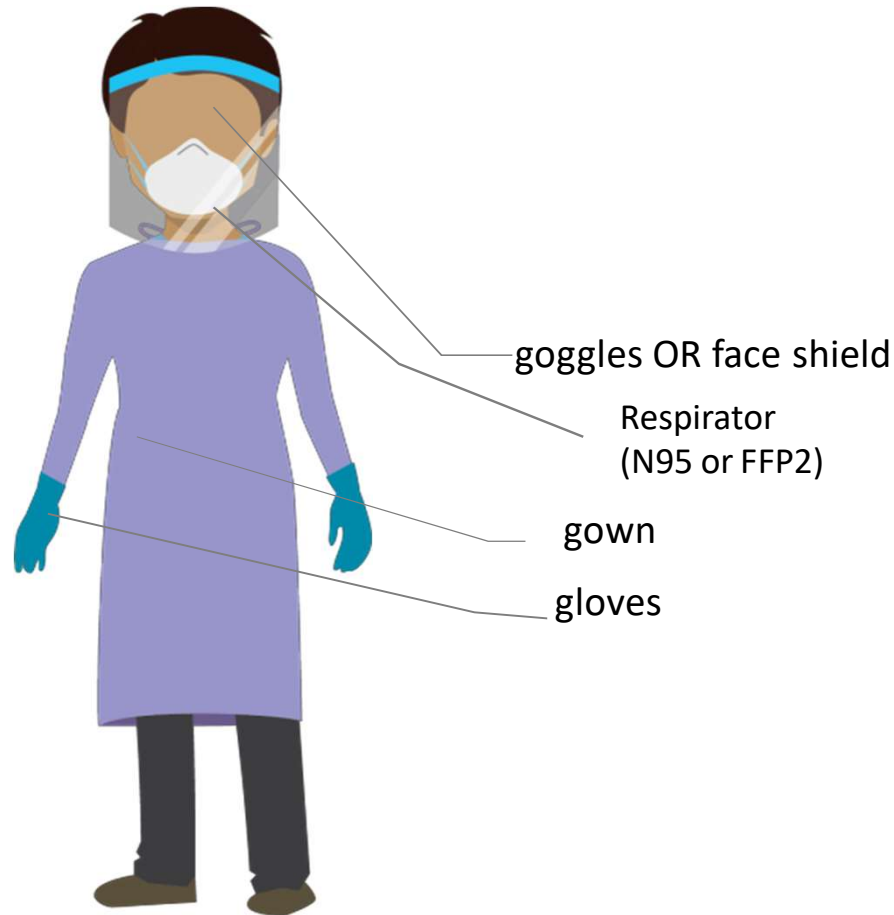
Types of PPE by activity

Triage/points of entry screening personnel



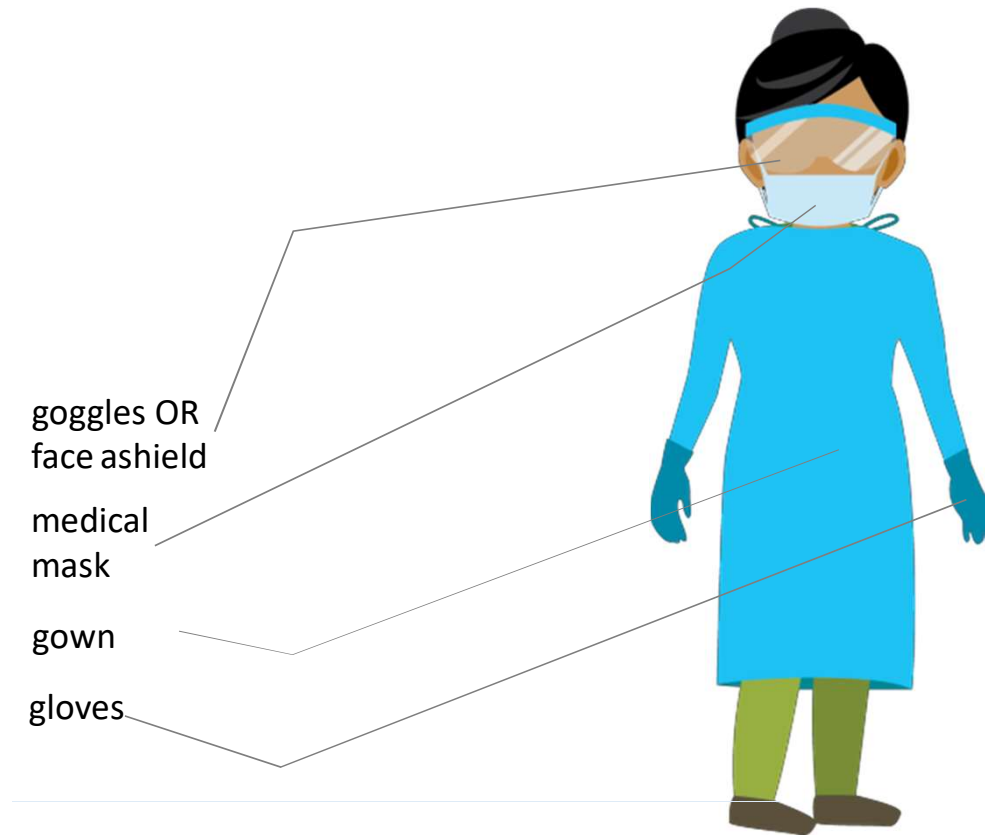
Types of PPE by activity

Collecting respiratory specimens



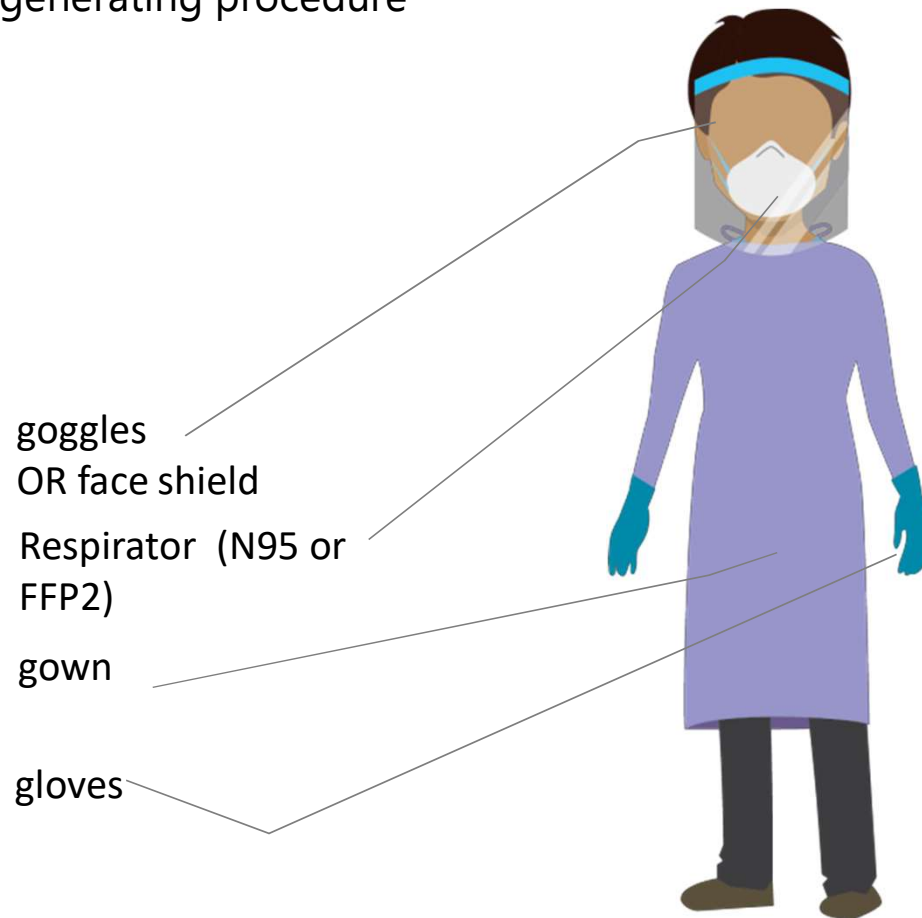
Types of PPE by activity

Transport of suspected/ confirmed case including direct care



Types of PPE by activity

Caring for a suspected/ confirmed case of COVID-19 WITH aerosol- generating procedure





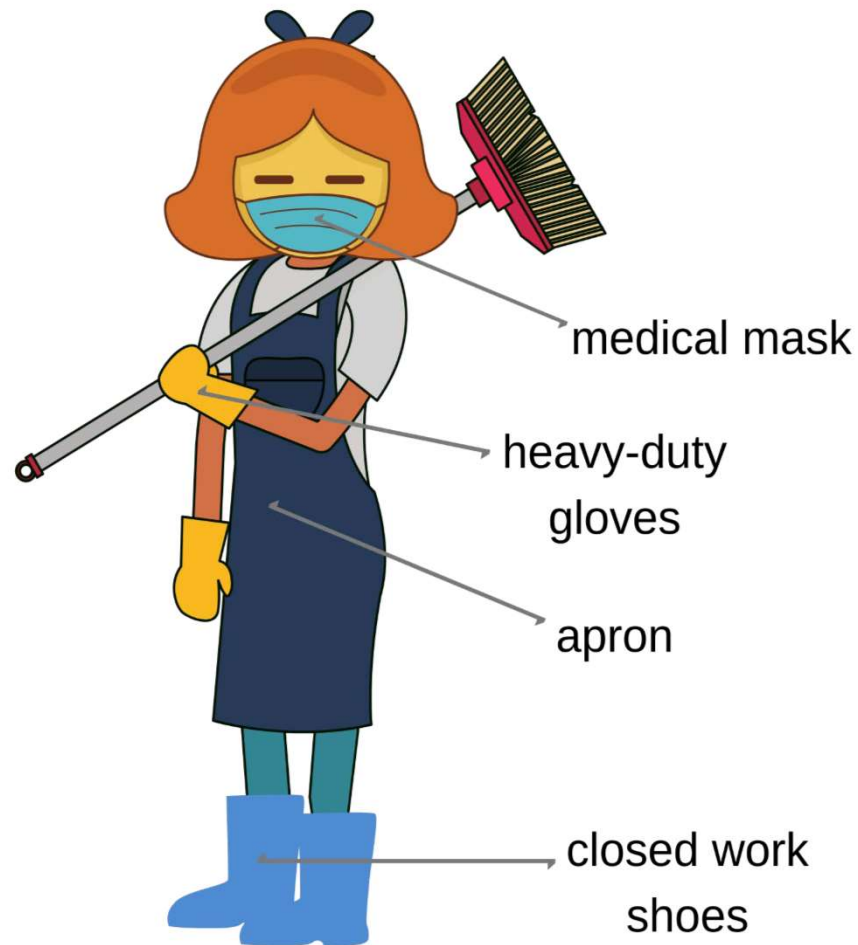
Types of PPE by activity

Caring for a suspected/confirmed case of COVID-19 with NO aerosol-generating procedure



Types of PPE by activity

Cleaning the room of COVID-19 patients



WHO Disease Commodity Package



Mask, surgical – healthcare worker

Technical description

- Surgical mask, good breathability, internal and external faces should be clearly identified
- Type II or higher.

Standards

- EU MDD Directive 93/42/EEC Category III or equivalent,
- EN 14683 Type II, IR, IIR
- ASTM F2100 minimum Level 1 or equivalent.

WHO Disease Commodity Package



Mask, surgical – patient

Technical description

- Surgical mask, good breathability, internal and external faces should be clearly identified
- Type I

Standards

- EN 14683 any type including Type I
- ASTM F2100 any level or equivalent

Example: Relevant standards



World Health Organization

Bangladesh

		USA: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS			EUROPE EN 14683:2019 Barrier Levels MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Splash resistance, synthetic blood ASTM F1862, ISO22609	Pass at 80 mm Hg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH2O/cm ²	<6.0 mmH2O/cm ²		<40 Pa/cm ²		<60 Pa/cm ²
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		<ul style="list-style-type: none"> AQL 4% for BFE, PFE, Delta P 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) 14 masks for Flammability 			<ul style="list-style-type: none"> Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness 32 masks for Synthetic Blood splash resistance (Pass = ≥29 passing, Fail = ≤28 passing) 		

WHO Disease Commodity Package



Particulate respirator, grade N95 or higher.

Technical description

- N95 or FFP2 respirator, or higher
- Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cupshaped).

Standards

- Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC NIOSH,
- Minimum "FFP2 according to EN 149, EU PPE Regulation 2016/425 Category III,
- or equivalent

WHO Disease Commodity Package



Gown

Technical description

- Single-use, length mid-calf.

Standards

- EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC
- FDA Class I or II medical device, or equivalent
- EN 13795 any performance level, or
- AAMI PB70 all levels acceptable, or equivalent

WHO Disease Commodity Package



Apron, heavy duty

Technical description

- Straight apron with bib,
- Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or other fluid-resistant coated material.
- Waterproof, sewn strap for neck and back fastening
- Minimum weight: 300 g/m²
- Covering size: 7090 cm (width) x 120–150 cm (height)
- Reusable (provided appropriate arrangements for decontamination are in place).

Standards

- EN ISO 13688
- EN 14126-B and partial protection (EN 13034 or EN 14605)
- EN 343 for water and breathability
- or equivalent

Bangladesh minimum testing requirements

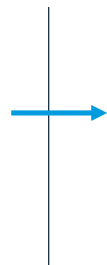


- ❑ **Technical working group established under DGDA**
- ❑ **Includes experts from BUET, Japanese inspection firm K2, and received advice from ICDDR,B**
- ❑ **Financial support from USAID and JICA**
- ❑ **Conducted a gap analysis of testing capacity of local laboratories**
- ❑ **Piloting minimum testing requirements in collaboration with five laboratories approved by DGDA**
- ❑ **Work in progress ...**

Gowns and Aprons:

Fluid Resistant

Disposable



Sterile

Non-Sterile



Level - 1

Level - 2

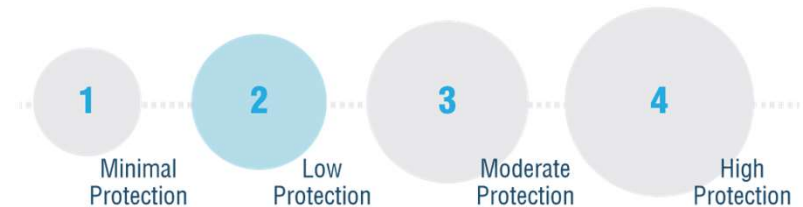
Level - 3

Level - 4



Special Conditions:

- All items MUST have product specification sheet
- All items Must have SOP to use and to dispose.
- All items Must be individually packaged;
- All items Must be latex free (surgical or non-surgical);
- All surgical items Must be supplied **Sterile**;
- All **Sterile items** Must be packaged in a **Sterile facilities**.



Gown: Fluid Resistant, Disposable, with elastic wrists

WHO Recommendation as minimum standard:

- **Option 1:** fluid penetration resistant: EN 13795 high performance, or AAMI PB70 level 3 performance or above, or equivalent.
- **Option 2:** blood borne pathogens penetration resistant: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent.

Possible Test Parameters:

- Tensile Strength (ASTM D5034, ASTM D1682)
- Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424)
- Seam Strength (ASTM D751 (stretch woven or knit))
- Water vapor transmission (breathability) (ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75)
- ~~Lint Generation (ISO 9073 Part 10)~~
- **Water Resistance: Hydrostatic Test (BS EN 13795:2019; AATC 127)**
- **Water Resistance: Impact Penetration Test (AATCC 42)**
- **Viral Penetration (ASTM F1671 or equivalent)**
- **Synthetic Blood Penetration (ASTM F1670 or equivalent)**



Gown: Disposable, with elastic wrists

WHO Recommendation as minimum standard:

- Option 1: fluid penetration resistant: EN 13795 high performance.
- Option 2: AAMI PB70 level 2 performance or above, or equivalent.

Possible Test Parameters:

- Tensile Strength (ASTM D5034, ASTM D1682)
- Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424)
- Seam Strength (ASTM D751 (stretch woven or knit))
- Water vapor transmission (breathability) (ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75; or equivalent (ASTM E96/E96M-16))
- Lint Generation (ISO 9073 Part 10)
- Water Resistance: Hydrostatic Test (BS EN 13795:2019; AATCC 127; or equivalent (e.g. AATCC 22, AATCC 35))
- Water Resistance: Impact Penetration Test (AATCC 42)



Surgical Mask

WHO Recommendation as minimum standard:

- EN 14683 Type IIR performance
- ASTM F 2100 level 2 or level 3 or equivalent
- Fluid resistance at minimum 120 mmHg pressure based on ASTM F1862-07, ISO 22609, or equivalent
- Filtration efficiency: ASTM F2101, EN14683 annex B or equivalent
- Breathability: MIL-M 36945C, EN 14683 annex C, or equivalent

Possible Test Parameters:

- **Splash Resistance (ASTM F1862-07), or equivalent**
- **Breathing Resistance, Differential Pressure (EN 14683:2019) , or equivalent**
- **Particulate Filtration Efficiency (F2299), or equivalent**
- **Test Bacterial Filtration Efficiency (F 2101), or equivalent**
- **Resistance to Penetration by Synthetic Blood (F 1862)**
- Perform Water Resistance Hydrostatic Test (BS EN 13795:2019; AATC 127)



N95 Mask

WHO Recommendation as minimum standard:

- Minimum "N95" respirator according to **FDA Class II, under 21 CFR 878.4040**, and CDC NIOSH, or equivalent
- Minimum **"FFP2 according to EN 149, EU PPE "**
- Regulation **2016/425 Category III**, or equivalent
- Fluid resistant surgical N95 respirator with **minimum 80 mm Hg pressure based on ASTM F1862, ISO 22606**, or equivalent

Possible Test Parameters:

- Breathing Resistance - MIL-M-3654C, or equivalent
- Breathing Resistance, Differential Pressure - EN 14683:2019, NIOSH 42 CFR 84.180, or equivalent
- Sub-Micron Particulate Filtration (F 2299), or equivalent
- Particulate Filtration Efficiency - NIOSH 42 CFR 84.181, or equivalent
- **Test Bacterial Filtration Efficiency (F 2101), or equivalent**
- **Resistance to Penetration by Synthetic Blood (F1862) , or equivalent**
- Perform Water Resistance Hydrostatic Test (BS EN 13795:2019; AATC 127)
- ~~Flammability (16 CFR Part 1610)~~
- ~~Biocompatibility - Irritation - ISO 10993-10~~
- ~~Biocompatibility - Sensitization - ISO 10993-10~~
- ~~Biocompatibility - Chemical Characterization - ISO 10993-18~~

N95 (95%) = FFP2 (94%)



KN95 (95%) = N95 (95%)



Thank you.
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Who we are, what we do

Our goal is to build a better, healthier future for people all over the world. WHO staff work side by side with governments and other partners to ensure the highest attainable level of health for all people. The primary role of WHO is to direct and coordinate international health within the United Nations' system.